

REMARKS UNDER 37 CFR § 1.116

Formal Matters

Claims 1,5-22,25-33,40-54,58-91,96-97,100-107,225,229-255,282 and 284-300 are pending after entry of the amendments set forth herein..

Claims 1,5-22,25-33,40-54,58-91,96-97,100-107,225,229-255,282 and 284-300 are examined.

Claims 1,5-22,25-33,40-54,58-91,96-97,100-107,225,229-255,282 and 284-300 were rejected.

Applicants respectfully request reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Office Action

Claims Rejected Under 35 U.S.C. Section 102(b) – Roth et al.

In the Official Action of March 28, 2006, claims 1, 9, 43-45, 106, 298 and 299 were rejected under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., U.S. Patent No. 5,207,672. In response to Applicants arguments that Roth et al. teaches against ablating, the Examiner referred to column 7, lines 49-53 and column 8, lines 47-55 of Roth et al. and asserted that Roth et al. allows for “minimized ablation”. These portions of Roth et al. refer to ultrasonic viewing to attempt to minimize the occurrence of ablation to maintain the activity in the “coagulation necrosis” regime. Thus, Roth et al.’s object is to damage the tissue by coagulation necrosis, so that the tissue dies and is later sloughed off during urination. This is not the same process as ablation, as is the subject of the present invention. Ablation according to the present invention causes a lesion of scar tissue which is not sloughed off, but remains to function as an electrical conduction block. See also, the background section of the present application at page 3, lines 20-24 that indicate that a potential disadvantage of RF ablation catheters is the risk of clot formation, which can cause potentially lethal strokes. Coagulation necrosis cause clots, and the sloughing off of such tissue would pose a significant risk to the procedures described in the present application.

Further, Roth et al. does not perform the coagulation necrosis transmurally, i.e., through the

entire width of the wall of the prostate, as this would cause a rupture of the prostate as the entire wall thickness would slough off. Figs. 11B-11C show that the coagulation necrosis is only performed through a portion of the wall of the prostate. Further, in the animal studies section, Roth et al. indicates that initial results were not satisfactory when the laser beam perforated the urethral tissue between the prostate and the bladder of the first two dogs treated. Although transmural ablation had previously been recited in claim 1, Applicants have further amended claim 1 to even more clearly differentiate over Roth et al. by reciting that a lesion formed by the transmural ablation forms an electric conduction block through an entire wall thickness of the tissue where the transmural ablation is performed. Claim 106 has been amended similarly. Support for these amendments can be found in the specification, for example at page 12, lines 25-29; page 15, lines 6-10; and page 25, lines 16-26, among others.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1, 9, 43-45, 106, 298 and 299 under 35 U.S.C. Section 102(b) as being clearly anticipated by Roth et al., U.S. Patent No. 5,207,672, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) – Lennox et al. in view of Costello et al.

Claims 1, 9, 43-45, 96, 97, 298 and 299 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in view of Costello et al., U.S. Patent No. 5,593,404. The Examiner asserted that Lennox et al. teaches the use of a flexible sheath with a window that can either be an open or a covered window for transmitting radiation to tissue. The Examiner asserted that Costello et al. teaches the equivalence of stationary and translatable energy applications, and that it would have been obvious to employ the probe translations and optics of Costello et al. in the method of Lennox et al. since these are equivalent to the stationary probe and can create a longer lesion. Alternatively, the Examiner asserted that it would have been obvious to employ the covered window and flexible sheath of Lennox et al. in the method of Costello et al., since this would keep the optic clean, and thus produce the presently claimed method.

Applicants respectfully disagree. Lennox et al. discloses a laser irradiation instrument having a flexible catheter. The instrument is used to treat hyperplasia of the prostate, and is configured to flow saline over the tissue surface to prevent charring of this tissue, while treating deeper tissue below the surface, see column 8, lines 23-43. Lennox et al. does not disclose or suggest transmurally ablating tissue such that a lesion formed by such transmural ablation forms an electric conduction block through an entire wall thickness of the tissue where the transmural ablation is performed.

Costello et al. also discloses a method of treating the prostate, and requires a hollow, rigid outer sheath to perform the method described. Costello et al. also fails to disclose or suggest transmurally ablating tissue such that a lesion formed by such transmural ablation forms an electric conduction block through an entire wall thickness of the tissue where the transmural ablation is performed. For the same reasons noted above with regard to Roth et al. and Lennox et al., it would not have been obvious to perform a transmural ablation during the method of Costello et al., as this would provide bad results, since the prostate would become perforated when the entire wall thickness sloughs off.

Accordingly, it is respectfully submitted that no proper combination of Lennox et al. and Costello et al. would meet all of the limitations of the rejected claims. The Examiner is therefore respectfully requested to reconsider and withdraw the rejection of claims 1, 9, 43-45, 96, 97, 298 and 299 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in view of Costello et al., U.S. Patent No. 5,593,404, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) – Lennox et al. in view of Costello et al. and Cox et al.

Claims 5-8, 10-22, 25-33, 40-42, 46-54, 58-72, 100-107, 225, 229-255, 282, 284-297 and 300 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Cox et al., WO 98/17187. The Examiner asserted that Cox et al. teaches the equivalence of laser, ultrasound microwave and cryosurgical energies as means of ablation, ablating tissue of the heart through a hole in the chest wall, use of a malleable end which can be pre-shaped, use of a sheath with a cut out window and various manipulation of a device including ablating around the pulmonary vein, ablating on the epicardium, and positioning the device in three or more positions. In view of this, the Examiner concluded that it would have been obvious to employ the maze procedure and ablation means of Cox et al. in the combined method of Lennox et al. and Costello et al. or to employ the combined teachings of Lennox et al. and Costello et al. in the method of Cox et al. since Cox et al. teaches no particular form for the non-cryogenic ablation elements.

Applicants respectfully disagree. With regard to the first suggestion, i.e., that it would have been obvious to employ the maze procedure and ablation means of Cox et al. in the combined method of

Lennox et al. and Costello et al., Applicants respectfully submit that this would result in the performance of a maze procedure on the prostate of a patient. It is respectfully submitted that there is no teaching or suggestion in any of these references that the performance of a maze procedure on the prostate would be advantageous, much less obvious.

As to employing the particular ablation steps of the combined teachings of Lennox et al. and Costello et al. in the method of Cox et al., it is respectfully submitted that this would also be disadvantageous and not obvious. As noted above, both Lennox et al. and Costello et al. teach away from transmural ablation, and rather teach necrosing the tissue so that it sloughs off. It would not have been obvious to employ these techniques with Cox et al., since they would not result in the performance of transmural ablations, and therefore the procedure would fail.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 5-8, 10-22, 25-33, 40-42, 46-54, 58-72, 100-107, 225, 229-255, 282, 284-297 and 300 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Cox et al., WO 98/17187, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Lennox et al. in view of Costello et al. and Swanson et al.)

Claims 70-79 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Swanson et al. It is respectfully submitted that these claims are allowable over the cited references for at least the same reasons provided above with regard to claim 1, since these claims depend from claim 1 and since Lennox et al. and Costello et al. are not properly combinable in the manner suggested by the Examiner for the reasons provided above with regard to claim 1.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 70-79 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in combination with Swanson et al., as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Lennox et al. in view of Costello et al. and Kesten et al.)

Claims 80-91 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in view of Kesten et al. It is respectfully submitted that these claims are allowable over the cited references for at least the same reasons provided above with regard to claim 1, since these claims depend from claim 1 and since Lennox et al. and Costello et al. are not properly combinable to meet all of the recitations of claim 1, for the reasons provided above with regard to claim 1.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 80-91 under 35 U.S.C. Section 103(a) as being unpatentable over Lennox et al., U.S. Patent No. 5,454,807, in combination with Costello et al., U.S. Patent No. 5,593,404, as applied to claims 1, 9, 43-45, 298 and 299 above, and further in view of Kesten et al., as being inappropriate.

Conclusion

Applicants submit that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-2653, order number GUID-117.

Respectfully submitted,

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Date: 7/12/06

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